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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/628,387	08/01/00	ROON-SHIONG	P ABI1150-10

HM12/0925
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EXAMINER	
PULLIAM, A	
ART UNIT	PAPER NUMBER
1615	6

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/628,387	SOON-SHIONG ET AL..	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/2/01* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-171* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-171* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of the Information Disclosure Statement, and the Amendment A, received June 15, 2001, and August 2, 2001, respectively.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-171 remain rejected under the judicially created doctrine of double patenting over claims 1-57 of U. S. Patent No. 6,096,331 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a unit dosage form comprising a taxane for systemic administration.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122,125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 remain provisionally rejected under the judicially created doctrine of double patenting over claims 1-78 of copending Application No. 09/628,389. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a unit dosage form comprising a taxane for systemic adminstration.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 remain rejected under 35 U.S.C. 102(b) as being anticipated by page 3553 of Drug Facts and Comparisons. This reference teaches that on December 29, 1992, the FDA approved paclitaxel for treatment. Further, the reference shows that the formulations which were approved are 135 mg/m^2 or 175 mg/m^2, administered intravenously over three hours every three weeks. This disclosure directly anticipates applicants claimed formulations and methods.

Applicant argues that the reference does not teach unit dosage forms, or describe single doses containing taxane in the range of about 30mg/m^2 to about 1000 mg/m^2. The examiner respectfully disagrees. The reference clearly teaches a single dosage of a taxane, in the amount of 135 mg/m^2 or 175 mg/m^2, to be administered over a three hour period. Applicant is asserting that there is a blatant difference between this reference and a unit dosage form, but it is the position of the examiner that the teaching of the reference *is* a unit dosage form. Furthermore, it is the position of the examiner

that a teaching to a single dosage form is the equivalent of a teaching to the recommended quantity of drug to be administered to a subject. In both instances, the teaching would disclose the specific amount of drug to be included in a formulation, which would be administered to a patient at one sitting. For these reasons, this rejection is maintained. Additionally, although applicant asserts that there is an important difference between "unit dosage form" and the teachings of the reference, it is unclear to the examiner what this difference is, and the examiner respectfully requests a clearer explanation of the asserted differences.

Claims 17-29, 45-57, 79-97, 102, 103, 108, 109, 114, 115, 120, 121, 126, 127, 132, 136, 142-144, 148, 152, 159, 163, 167, 169, and 171 remain rejected under 35 U.S.C. 102(b) as being anticipated by page 3558 of Drug Facts and Comparisons. This reference teaches that on May 14, 1996 the FDA approved docetaxel for treatment. Further, the reference shows that the formulations which were approved are 60 mg/m^2 to 100 mg/m^2, administered intravenously over an hour every three weeks. This disclosure directly anticipates applicants claimed formulations and methods.

Applicant argues that the reference does not teach unit dosage forms, or describe single doses containing docetaxel in the range of about 40mg/m^2 to about 800 mg/m^2. The examiner respectfully disagrees. The reference clearly teaches a single dosage of docetaxel, in the amount of 60 mg/m^2 to 100 mg/m^2, to be administered over a one hour period. Applicant is asserting that there is a blatant difference between this reference and a unit dosage form, but it is the position of the examiner that the teaching

of the reference *is* a unit dosage form. Furthermore, it is the position of the examiner that a teaching to a single dosage form is the equivalent of a teaching to the recommended quantity of drug to be administered to a subject. In both instances, the teaching would disclose the specific amount of drug to be included in a formulation, which would be administered to a patient at one sitting. For these reasons, this rejection is maintained. Additionally, although applicant asserts that there is an important difference between "unit dosage form" and the teachings of the reference, it is unclear to the examiner what this difference is, and the examiner respectfully requests a clearer explanation of the asserted differences.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, and 137-141 remain rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,683,715 to Boni *et al.*. Boni *et al.* disclose taxane formulations useful in the treatment of cancers. More specifically, Boni *et al.* teach of paclitaxel in a formulation for administration to an animal, preferably a human, wherein the animal is afflicted with a cancer and the composition comprises an anticancer effective amount of paclitaxel (c 11-12, claims 1-13). Boni *et al.* further teach that the anticancer effective amount of paclitaxel is from about 1 mg/kg to 500 mg/kg (c 12, claim 14). The above stated claims are composition claims, and Boni *et al.* teaches applicant's claimed drug for treatment of cancer, therefore, anticipating applicant's composition claims.

Applicant argues that the reference does not teach unit dosage forms comprising taxane. Applicant further argues that the reference does not teach the administration protocols required by applicant's claims. The examiner respectfully disagrees for the reasons stated in the rejection. Additionally, applicant is asserting that there is a blatant difference between this reference and a unit dosage form, but it is the position of the examiner that the teaching of the reference *is* a unit dosage form. Furthermore, it is the position of the examiner that a teaching to a single dosage form is the equivalent of a teaching to the recommended quantity of drug to be administered to a subject. In both instances, the teaching would disclose the specific amount of drug to be included in a formulation, which would be administered to a patient at one sitting. For these reasons, this rejection is maintained. Additionally, although applicant asserts that there is an important difference between "unit dosage form" and the teachings of the reference, it is unclear to the examiner what this difference is, and the examiner respectfully requests a clearer explanation of the asserted differences.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153-154, 156-158, 160-162, 164-168, and 170 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,648,090 to Rahman. Rahman teaches formulations of taxol (paclitaxel). More specifically, Raqhman teaches that taxol and its derivatives can be used to treat any form of mammalian cancer (c 8, l 5-10). Further, Rahman teaches that the taxol formulations of his invention are generally administered intravenously to the mammal, in the amount of

50-250 mg active compound/ m^2 of the mammalian host (c 8, l 12-21). Therefore, Rahman anticipated the above listed claims because he teaches the composition, method of treatment, and the method of administration.

Applicant argues that the reference does not teach unit dosage forms comprising taxane. Applicant further argues that the reference does not teach the administration protocols required by applicant's claims. The examiner respectfully disagrees for the reasons stated in the rejection. Additionally, applicant is asserting that there is a blatant difference between this reference and a unit dosage form, but it is the position of the examiner that the teaching of the reference *is* a unit dosage form. Furthermore, it is the position of the examiner that a teaching to a single dosage form is the equivalent of a teaching to the recommended quantity of drug to be administered to a subject. In both instances, the teaching would disclose the specific amount of drug to be included in a formulation, which would be administered to a patient at one sitting. For these reasons, this rejection is maintained. Additionally, although applicant asserts that there is an important difference between "unit dosage form" and the teachings of the reference, it is unclear to the examiner what this difference is, and the examiner respectfully requests a clearer explanation of the asserted differences.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-171 rejected under 35 U.S.C. 103(a) as being unpatentable over page 3553 or page 3558 of Drug Facts and Comparisons as applied above. The reference does not specifically state the mg amounts as claimed by applicant in claims 58 –78. However, the reference does teach the same concentration amounts, thereby implying that the dosages contain the same amounts, especially as they are used for the same purpose, over the same period of time. One of ordinary skill in the art would have been motivated to make a pharmaceutical formulation of a taxane, either paclitaxel or docetaxel, based on the disclosure in Drug Facts and Comparisons, as the formulations claimed by applicant are taught in the reference for each of these drugs. The expected result would be a successful antitumor formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant argues that their invention distinguishes over the references by requiring unit dosage forms comprising a contained containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. The examiner repeats the response to the 102 rejections, as stated above.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153-154, 156-158, 160-162, 164-168, and 170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boni *et al.* as applied in the 35 U.S.C. 102(e) rejection above. Boni *et al.* is discussed above as teaching a pharmaceutical formulation for the treatment of an animal, comprising the drug paclitaxel. Boni *et al.* does not specifically teach applicant's claimed method. However, is it the position of the examiner that based on Boni *et al.*'s teaching to administer paclitaxel for the treatment of cancer, the specifics of this method are manipulatable parameters which would be obvious to vary to one of skill in the art, depending on the type of cancer, the size and weight of the patient, the severity of the illness, and the health of the patient. One of ordinary skill in the art would have been motivated to vary the method of administration based on these characteristics. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This rejection is maintained for reasons previously stated.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153-154, 156-158, 160-162, 164-168, and 170 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,648,090 to Rahman as applied in the above 35 UI.S.C. 102(e) rejection. Rahman is discussed above as teaching the composition and method as claimed by applicant. Rahman does not teach all of the specific parameters in applicant's claimed method

claims. However, is it the position of the examiner that based on Rahman's teaching to administer taxol for the treatment of cancer, the specifics of this method are manipulatable parameters which would be obvious to vary to one of skill in the art, depending on the type of cancer, the size and weight of the patient, the severity of the illness, and the health of the patient. One of ordinary skill in the art would have been motivated to vary the method of administration based on these characteristics. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This rejection is maintained for reasons previously stated.

Claims 1-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boni *et al.* or Rahman as applied above, and further in view of US Patent 5,977,163 to Li *et al.*. Boni *et al.* and Rahman are discussed above as teaching applicant's composition and method comprising paclitaxel. However, neither Boni *et al.* nor Rahman disclose the use of docetaxel as the antitumor agent. Li *et al.* is relied upon for the teaching that it is known in the art that docetaxel and paclitaxel are both well known anticancer agents, and can b used interchangeably in antitumor formulations (c 20, claim 1). One of ordinary skill in the art would have been motivated to use any well known antitumor agent in the formulations disclosed by Boni *et al.* or Rahman *et al.*, as both references disclose formulations for the treatment of cancer. One of ordinary skill in the art would expect another well known cancer agent to have the same effects as

paclitaxel. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This rejection is maintained for reasons previously stated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

aep
September 21, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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